DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 5, 2014

Schoelly Fiberoptic GmbH
Ms. Pamela Papineau, RAC
Delphi Medical Device Consulting Incorporated
5 Whitcomb Avenue
Ayer, Massachusetts 01432

Re: K143221
Trade/Device Name: Schoelly Laparoscope
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: November 6, 2014
Received: November 10, 2014

Dear Ms. Papineau:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143221

Device Name
Schoelly Laparoscope

Indications for Use *(Describe)*

The Schoelly Laparoscope is indicated for examination of body cavities, hollow organs, and canals, and using additional accessories, to perform various diagnostic and therapeutic procedures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

Section 5 – Special 510(k) Summary

General Information

Preparation date: 11/06/2014

Owner's Name: Schoelly Fiberoptic GmbH (Registration: 8043903)
Address: Robert-Bosch-Str. 1 – 3
79211 Denzlingen
Germany

Telephone Number: +49-7666-980-0
Fax Number: +49-7666-908-380
Contact Person: Dr. Sandra Baumann

Subject Device Name: Schoelly Laparoscope
Trade Name: Schoelly Laparoscope
Common/Usual Name: Laparoscope
Classification Name: GCJ – Laparoscope, General & Plastic Surgery
21 CFR 876.1500; Class II

Predicate Device Name: Schoelly Laparoscope
Trade Name: Schoelly Rigid Endoscope
Common/Usual Name: Laparoscope
Classification Name: GCJ – Laparoscope, General & Plastic Surgery
21 CFR 876.1500; Class II
Premarket Notification: K992437 (Schoelly Inc. /formerly known as Fiber Imaging Technologies, Inc.) SE date September 14, 1999

Device Description

The Schoelly Laparoscope is a rigid reusable endoscope for visualization of body cavities used in conjunction with a commercially available and approved light guide, light source, video camera, monitor, and printer. Light guide, light source, video camera, monitor, and printer are not included in the scope of delivery and are further not within the scope of this application.

Light that is created by an external light source is transmitted from the laparoscope light guide connector through the laparoscope itself to the tip via a fiber optic system. Images are transferred the other way back through a rigid rod lens system.

Schoelly Laparoscopes are manufactured in multiple configurations that differ in insertion tube outer diameter and working length and with respect to optical parameters (direction of view, field of view).

Like other currently marketed laparoscopes, the proposed device has outer surfaces mainly made from metal (304 stainless steel) and further comprise fiber optics for light transmission and rigid rod-lenses for image transmission.

The Schoelly Laparoscope is delivered in a non-sterile condition and is already CE marked.

Indications for Use
The Schoelly Laparoscope is indicated for examination of body cavities, hollow organs, and canals, and using additional accessories, to perform various diagnostic and therapeutic procedures.

Predicate Device
The predicate device is identical to the proposed device with the same device specifications and design, the same indications for use, and the same fundamental scientific technology. The changes described in this submission are limited to a change of device materials and the addition of new device configurations that differ with respect to geometric dimensions of the endoscope insertion tube as compared to the predicate device that was cleared for marketing by FDA in K992437. These changes do not in any way alter the device indications for use, or the fundamental scientific technology upon which the device is based.

Performance Testing
This 510(k) contains a summary of the biocompatibility testing conducted in accordance with ISO 10993-1 (cytotoxicity, irritation, sensitization and acute systemic toxicity).

Conclusion
The proposed modification to the Schoelly Laparoscope has met all predetermined acceptance criteria as specified by applicable standards, test protocols, and/or customer inputs and does not introduce new patient or user risks. The device with the changed material and additional dimensional configurations is substantially equivalent to the predicate device.